



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,473	05/31/2000	BARBARA BOTTAZZI	2801-18	9420

23117 7590 04/20/2005

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,473

Applicant(s)

BOTTAZZI ET AL.

Examiner

Patrick J. Nolan

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1/1

Art Unit: 1644

1. Claims 17-19 are pending.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 17-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brevario et al., in view of US Patent 6,344,320, both of record, for reasons of record in the Office Action mailed 9-23-04.

Applicant's arguments filed 1-21-05 have been fully considered but are not found persuasive.

Applicant argues there is no teaching in Brevario on how to make PTX3 and that Brevario et al., teaches that the protein is a putative protein and likely to be relatively unstable.

However, it is noted that the full amino acid sequence is taught by Brevario et al. in Figure 1B. Furthermore, the '320 specifically teaches making nascent proteins in cell free assay systems, wherein the starting material is the cDNA or mRNA sequence, such sequence is taught by Brevario et al. Lastly, it is important to note that Applicant's own specification provides no teaching on how to make the full length PTX3, 381 amino acid sequence. At best, the teachings of the specification would create a mature secreted sequence made in eukaryotic cells that is 363 amino acids long, see page 5 in particular. In contrast the cell free assay system taught by the '320 patent would result in the production of the full 381 amino acid sequence.

Applicant argues an unexpected result for their claimed invention.

However, Attorney's arguments are not evidence where evidence is required, see MPEP 2145.

Applicant argues there is no motivation to make a pharmaceutical composition out of PTX3 and that Examiner relies upon the '320 for said motivation.

Art Unit: 1644

The pending claims are composition claims. The requisite motivation to place the PTX3 protein in PBS or saline, a pharmaceutical excipient, is present in the teachings of Brevario et al., would clearly teach that “the PTX3 gene reported here has characteristics that make it attractive as a potential marker for inflammatory conditions... Thus PTX3 may complement the classical pentraxins and represent a novel indicator of tissue reactions, particularly those involving the vessel wall” (page 22196, 2nd column, the end, in particular). One of skill in the art reading that statement would be clearly motivated to study the purported functions of PTX3 and in order to do that they would be clearly motivated to make it and put it in a pharmaceutical composition as taught by the ‘320 patent, since the ‘320 patent clearly teaches making any protein for diagnostic or therapeutic testing and putting said made protein in a pharmaceutical composition for said testing.

Applicant argues the ‘320 patent provides no teachings in regards to PTX3 and so it cannot be used as motivation to put make PTX3 and put into a pharmaceutical composition.

The ‘320 patent is relied upon for general knowledge of how one of skill in the art would make a protein of interest and study that protein, in vivo or in vitro. Motivation for why one of ordinary skill in the art would be interested in studying PTX3 further comes from Brevario et al.

Applicant argues the cell free translation systems of the ‘320 patent contain the same impurities that have been demonstrated by evidence in the record to not constitute a pharmaceutically acceptable excipient or solution.

However, column 15 of the ‘320 patent specifically teaches purifying the proteins made in the cell free assay.

Applicant argues against various embodiments of the cell free assay system taught by the ‘320 patent.

Art Unit: 1644

However, they do not argue against the use cell free assays in general in a persuasive to provide evidence that the cell free assays taught by the '320 patent using the sequence taught by Brevario et al., would not result in a pharmaceutical composition comprising SEQ ID NO. 1 in a pharmaceutically acceptable excipient.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Application/Control Number: 09/555,473

Page 5

Art Unit: 1644

A handwritten signature in black ink, appearing to read "Pat J. Nolan", written in a cursive style.

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

April 8, 2005